

3/29/99

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

K 983496

Applicant information:

Date Prepared:	October 1, 1998
Name:	Opti-Center Laboratories Inc.
Address:	4375 Ouimet Street Sherbrooke (Quebec) Canada J1L 1X5
Contact Person:	Robert Mercure
Phone number:	(819) 564-8114
USA Consultant:	Med-Vice Consulting, Inc.
	Martin Dalsing
Phone number:	(970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear contact Lens, (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)

Equivalent Devices:

The Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear Contact Lenses are substantially equivalent to the following predicate devices in terms of intended use and design. Predicate devices include: "Horizon 55 Spherical & Westthin Toric" manufactured by Westcon Contact Lens, and the "BENZ-G 3X" manufactured by Benz Research and Development.

Device Description:

The Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear Contact Lenses are fabricated from hioxifilcon B, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (hioxifilcon B) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 48% water by weight. The physical properties of the lens are:

Refractive Index	1.515 (dry) 1.404 (hydrated)
Color Pigment Name	Phthalocyanine Blue
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	48 % ± 2%
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The Resolution 45 (Spherical) (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The Ultra Gel (Toric) (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Opti-Center Laboratories, Inc. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X, 510(k) #K964528. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates the production method, lens function and material characteristics of the Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank), as well as the predicate devices.

Substantial Equivalence Matrix

	Characteristic	Resolution 45 (Spherical)	Ultra Gel (Toric)	PREDICATE DEVICES
1.)	PRODUCTION METHOD	Lathe-Cut	Lathe-Cut	Lathe-Cut
2.)	LENS FUNCTION	Refractive medium that focuses light rays from distant, intermediate and near objects on the retina, while compensating for refractive error.	Refractive medium that focuses light rays from near, intermediate and distant objects on the retina, while compensating for refractive error.	Refractive medium that focuses light rays from near, intermediate and distant objects on the retina, while compensating for refractive error.
3.)	MATERIAL	Hydrophilic Polymer	Hydrophilic Polymer	Hydrophilic Polymer
a.	Water Content	48%	48%	55%, 48%
b.	Polymer Content	52%	52%	45%, 52%
c.	Polymer	hioxifilcon B	hioxifilcon B	methafilcon A, hioxifilcon B
d.	DK Value	15	15	18.2, 15
e.	Refractive Index	1.404 (hydrated)	1.404 (hydrated)	1.408, 1.404
f.	Specific Gravity	1.136 (hydrated)	1.136 (hydrated)	1.090, 1.136
g.	Light Transmission	greater than 95% T	greater than 95% T	greater than 95% T



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 1999

Mr. Martin Dalsing
Official FDA Correspondent
Opti-Center Laboratories
623 Glacier Drive
Grand Junction, CO 81503

Re: K983496

Trade Name: Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear
Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)

Regulatory Class: II

Product Code: 86 LPL

Dated: January 20, 1999

Received: January 26, 1999

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, reading "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: Resolution 45 (Spherical) and Ultra Gel (Toric) (hioxifilcon B) Soft Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)

INDICATIONS FOR USE:

The Resolution 45 (Spherical) (hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Cheng-Chuan Shih
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K 983496

or

Over-The-Counter Use

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)